UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION	)	
This Document Relates to:	)	
ADELE N. BURKE, Plaintiff,	)	CIVIL ACTION NO. 7:15-cv-00083
vs.	)	MDL Docket No. 3:11-MD-2244-K
DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON, INC., and DOES 1-10, inclusive, Defendants.	)	**JURY TRIAL DEMANDED**

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW Plaintiff, by and through her undersigned attorneys, and, for her Complaint against the Defendants, DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON, INC., and DOES 1-10 INCLUSIVE, alleges as follows:

I. PARTIES

1. Plaintiff, Adele N. Burke, is a citizen of the State of North Carolina and resides in Southport, Brunswick County, North Carolina.

2. Upon information and belief, Defendant DEPUY ORTHOPAEDICS, INC., ("DEPUY") is, and at all times relevant to this Complaint was, a corporation organized and existing under the laws of Indiana with its principal place of business at 700 Orthopaedic Drive,

Warsaw, Indiana 46581. Upon information and belief, DEPUY does not maintain a principal local office in North Carolina. DEPUY's registered agent for service is CT Corporation System, 150 Fayetteville Street, Box 1011, Raleigh, North Carolina 27601.

3. At all relevant times to this Complaint, Defendant DEPUY designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including the Plaintiff, Adele N. Burke, in the County of Brunswick, State of North Carolina.

4. Upon information and belief, Defendant JOHNSON & JOHNSON SERVICES, INC. ("J&J SERVICES") is, and at all times relevant to this Complaint was, a corporation organized and existing under the laws of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Upon information and belief, J&J SERVICES does not maintain a principal local office in North Carolina. J&J SERVICE's registered agent for service is CT Corporation System, 150 Fayetteville Street, Box 1011, Raleigh, North Carolina 27601.

5. At all relevant times to this Complaint, Defendant J&J SERVICES, as the parent company of DEPUY, designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States including the Plaintiff Adele N. Burke, in the County of Brunswick, State of North Carolina.

6. Upon information and belief, Defendant JOHNSON & JOHNSON, INC. ("J&J") is, and at all times relevant to this Complaint was, a corporation organized and existing under the laws of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Upon information and belief, J&J does not maintain a principal

local office in North Carolina. J&J's registered agent for service is Douglas K. Chin, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

7. At all relevant times to this Complaint, Defendant J&J, as the parent company of DEPUY, designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States including the Plaintiff Adele N. Burke, in the County of Brunswick, State of North Carolina.

8. The true names and capacities of Defendants DOES 1-10, inclusive, are unknown to Plaintiff. Plaintiff is informed and believes and thereon alleges that each of these Defendants are in some way liable for the events referred to in this Complaint and caused damage to Plaintiff. Plaintiff will amend this Complaint and insert the correct names and capacities of those Defendants when they are discovered.

9. At all times mentioned, each of the Defendants – including DOES 1-10 – was the representative, agent, employee, joint venture, or alter ego of each of the other defendants and in doing the things alleged herein was acting within the scope of its authority as such.

10. DEPUY, J&J SERVICES, J&J and DOES 1-10 are collectively referred to herein as "Defendants".

II. JURISDICTION AND VENUE

11. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and no Defendant is a citizen of the same state as Plaintiff.

12. Venue is proper in this Court because Plaintiff resides in Southport, North Carolina and the actions of the Defendants that give rise to this Complaint took place, in part, in North Carolina.

III. FACTUAL BACKGROUND

A. DePuy's Pinnacle Hip is Unsafe and Has Not Been Adequately Tested

13. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

14. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem; (2) a femoral head; (3) a plastic (polyethylene) liner; and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

15. The Pinnacle Hip has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular liner. The design of the Pinnacle Hip was not sufficiently tested by the Defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

16. The Pinnacle Hip is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

17. The Medical Device Amendments to the Food, Drug and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Hip, to undergo

premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

18. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

19. The FDA may grant premarket approval only if it finds that this is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

20. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval.

21. In addition, a medical device marked *after* the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then clear the new device for sale in the United States.

22. The MDA does not require an FDA determination that the device is, in fact, substantially equivalent to a grandfathered device.

23. Instead of assuring the safety of the Pinnacle Hip through clinical trials, DEPUY sought to market its Pinnacle Hip without conducting any clinical trials by obtaining FDA approval under Section 510(k). To that end, Defendants submitted a Section 510(k) premarket notification of intent to market the Pinnacle Hip.

24. By telling the FDA that the Pinnacle Hip's design was "substantially equivalent" to other hip products on the market, DEPUY was able to avoid the safety review required for premarket approval under FDA regulations, including clinical trials.

25. The FDA cleared the Pinnacle Hip for sale by means of the abbreviated 510(k) process and consequently, the FDA did not require the Pinnacle Hip to undergo clinical trials.

26. The 510(k) notification for the Pinnacle Hip includes only Defendant DEPUY's assertion that it believes the DEPUY Pinnacle Hip to be substantially equivalent to devices that themselves had never been reviewed for safety and effectiveness.

27. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny – or even clinical testing – of a device's safety and effectiveness.

28. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness. This point is forcefully underscored by the FDA's letter to DEPUY, which says nothing about the safety and effectiveness of the Pinnacle Hip; finds only that the device was "substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976"; and concludes by stressing that the agency's determination of substantial equivalence "does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."

29. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle Hip's safety and effectiveness, but rather only a determination of equivalence to devices that themselves underwent no safety and effectiveness review.

30. While most hip replacements use a polyethylene ***plastic*** acetabular liner, DEPUY's Pinnacle Hip has a critical difference: it uses a ***metal*** acetabular liner. By using a metal acetabular liner and a metal femoral ball, the Pinnacle Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the Pinnacle Hip, hundreds of patients – including Ms. Burke – have been forced to undergo surgeries to replace the failed hip implants.

31. Plaintiff believes that the Pinnacle Hip suffers from a similar design or manufacturing defect that forced DEPUY to recall over 93,000 metal-on-metal ASR and ASR XL hip implants. While the exact nature of the common defect is still being investigated, Plaintiff believes that both hip implants suffer from one or more similar design or manufacturing defects that cause excessive amounts of cobalt and chromium to wear from the surface of the acetabular insert or from the femoral head. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

B. DEPUY Should Have Recalled The Pinnacle Hip Years Ago; Over 1,300 Adverse Events Related To The Pinnacle Hip Have Been Reported

32. It was not long after DEPUY launched the Pinnacle Hip that reports of failures began flooding into DEPUY. For example, on May 4, 2002, DEPUY received a complaint that a

patient had to undergo a surgery to remove and replace the hip implant because the liner disassociated with the cup. DEPUY closed its investigation of this complaint, finding that "corrective action is not indicated." Two weeks later, on May 17, 2002, DEPUY received another report that another patient had to undergo surgery to remove and replace a defective hip implant because the acetabular cup had loosened. Again, DEPUY closed its investigation of this complaint, finding that "corrective action is not indicated."

33. DEPUY would go on to receive hundreds of similar complaints reporting that the Pinnacle Hip had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component.

34. By the time DEPUY sold the Pinnacle Hip to Adele N. Burke in May 2003, DEPUY was fully aware that the Pinnacle Hip was defective and that several patients already had been injured by that defect. Based on this information, DEPUY should have recalled the Pinnacle Hip before it was sold to Ms. Burke. At minimum, DEPUY should have stopped selling the defective implant when it became aware that it has catastrophically failed in several patients.

35. Over the next two years, reports that the Pinnacle implant had failed were flooding into DEPUY. For example, by the end of 2008, DEPUY had received more than 430 reports and by the end of 2009, that number had skyrocketed to almost 750. To date, DEPUY has received an astonishing ***1,300 reports*** associated with Pinnacle Hips.

36. Despite its knowledge that the Pinnacle Hip had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DEPUY continued to sell the defective hip implant. In so doing, DEPUY actively concealed the

known defect from doctors and patients – including Ms. Burke and her doctor – and misrepresented that the Pinnacle Hip was a safe and effective medical device.

37. DEPUY's reason to conceal the defect in its Pinnacle Hip is clear. In 2009 alone, DEPUY brought in more than $5.4 billion in sales. Hip implant sales are critically important to DEPUY's parent company, J&J, and DEPUY is one of J&J's most profitable business groups. In 2008, DEPUY was faced with a critical defect in one of its hip implant system. The last thing DEPUY wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, DEPUY decided that it would not issue an embarrassing recall when it learned of the defects with its Pinnacle Hip. Moreover, motivated by greed rather than patient safety, DEPUY did not even stop selling the Pinnacle Hip. Instead, it continued to manufacture the hip implants and it continued to sell them to unsuspecting patients like Ms. Burke. To this day, DEPUY continues to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

38. Defendants continued to sell the Pinnacle Hip to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudo tumors and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

C. Ms. Burke's Pinnacle Hip Was Defective and Failed, Forcing Her to Undergo an Additional Painful and Risky Surgery

39. On May 1, 2003, Ms. Burke underwent a surgical procedure performed by Dr. Wolfgang Fitz at Faulkner Hospital in Boston, MA. A Pinnacle Hip was implanted in her right hip. By this time, Defendants already knew that the Pinnacle Hip was defective, but Defendants refused to disclose that information to Ms. Burke, her physicians, or the public.

40. After the surgery, friction and wear between the metal head and metal liner caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Plaintiff's blood and tissue and bone surrounding the implants. As a result, Plaintiff has been experiencing severe pain, discomfort and inflammation in and around her implant, and elevated levels of cobalt and chromium in her bloodstream.

41. Due to Plaintiff's chronic pain, discomfort, high levels of cobalt and chromium in her bloodstream, and other symptoms, Plaintiff's doctors have recommended that she undergo a painful, complex and risky surgery, known as a "revision surgery", to remove and replace the Pinnacle Hip in her right hip that had failed. On March 26, 2015, Ms. Burke underwent a revision surgical procedure performed by Dr. Walter Frueh at New Hanover Regional Medical Center in Wilmington, NC.

42. Plaintiff only recently became aware of the causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device and to the failure of Defendants to properly warn her and her physicians about the Pinnacle Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence, because of Defendants' failure to properly warn her and her physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

43. All of the injuries and complications suffered by Plaintiff were caused by the defective design, lack of adequate warnings, construction and unreasonably dangerous character of the Pinnacle Devices that were implanted in her. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Devices, Plaintiff would not have consented to the Pinnacle Device being used in her total hip arthroplasty.

44. Having to go through revision surgery will subject Ms. Burke to a much greater risk of future complications than she had before the revisions surgeries. For example, several studies have found that just one revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20-26.)

45. As a direct and proximate result of the failure of the defective Pinnacle Hip and Defendants' wrongful conduct, Ms. Burke sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Ms. Burke has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the jurisdictional minimum of this court.

COUNT I
(Negligence)

46. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

47. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects.

48. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle Device into interstate commerce. Defendants knew or should have known that those individuals who had the device surgically implanted were at risk for suffering harmful effects from it, including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Additionally, Defendants knew or should have known about the harmful effects from the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

49. The negligence of Defendants, their agents, servants and employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Pinnacle Device in a manner that was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating and promoting the Pinnacle Device without adequately, sufficiently or thoroughly testing it;

c. Not conducting a sufficient testing program to determine whether or not the Pinnacle Device was safe for use;

d. Marketing and selling the Pinnacle Device when Defendants knew or should have known that it was unsafe and unfit for use because of the dangers to its users;

e. Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;

f. Negligently failing to adequately and correctly warn Plaintiff or her physicians, hospitals and healthcare providers of the dangers of the Pinnacle Device;

g. Negligently failing to recall their dangerous and defective Pinnacle Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding safety precautions to be observed by the surgeons who would reasonably and foreseeably come in contact with, and more particularly, implant the Pinnacle Device into their patients;

i. Negligently advertising and recommending the use of the Pinnacle Device despite the fact Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Pinnacle Device offered low wear and high stability, when, in fact, the opposite was true;

k. Negligently manufacturing the Pinnacle Device in a manner that was dangerous to those individuals who had it implanted;

l. Negligently producing the Pinnacle Device in a manner that was dangerous to those individuals who had it implanted;

m. Negligently assembling the Pinnacle Device in a manner that was dangerous to those individuals who had it implanted; and

n. Negligently under-reporting, underestimating and downplaying the serious dangers of the Pinnacle Device.

50. Defendants were further negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

e. Were otherwise careless and negligent.

51. Despite the fact that Defendants knew or should have known that the Pinnacle Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and sell the Pinnacle Device.

52. Defendants knew or should have known that consumers, such as Plaintiff, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

53. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss, which she has suffered and will continue to suffer in the future.

54. By reason of the foregoing, Plaintiff experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiff also underwent revision surgery to replace the device, which carries the attendant risk of complications and death from such surgery.

55. In performing the foregoing acts and omissions, Defendants acted grossly negligent, fraudulently and with malice so as to justify an award of punitive and/or exemplary damages.

COUNT II
(Products Liability Act – Failure to Warn)

56. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

57. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Pinnacle Hip, including the Pinnacle acetabular cup, the Pinnacle metal liner, and the ASphere M-Spec metal-on-metal femoral head, and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Pinnacle Hip.

58. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her physician, of the true risks of the Pinnacle Hip, including that the Pinnacle Hip could loosen and separate from the hip socket, and/or cause a toxic metal reaction, causing severe pain and injury, and requiring further treatment, including revision surgery and/or replacement.

59. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Pinnacle Hip. Had they done so, proper warnings would have been heeded and no health care professional, including Ms. Burke's physician, would have used the Pinnacle Hip and no patient, including Ms. Burke, would have had the Pinnacle Hip implanted.

60. Defendants failed to provide timely and reasonable instructions and training concerning the safe and effective use of the Pinnacle Hip to either Ms. Burke or her physician.

61. The Pinnacle Hip, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released

into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Ms. Burke, and continued to aggressively promote the Pinnacle Hip.

62. Defendants failed to perform or otherwise facilitate adequate testing, failed to reveal or concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

63. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

COUNT II
(Products Liability Act – Defective Design)

64. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

65. Defendants are the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of the Pinnacle Hip, which is defective and unreasonably dangerous.

66. The Pinnacle Hip is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The Pinnacle Hip is defective in design in that it lacks efficacy, poses a greater likelihood of injury and is more dangerous than other available devices indicated for the same conditions and uses.

67. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the Pinnacle Hip did not outweigh its risks.

68. The defective condition of the Pinnacle Hip rendered it unreasonably dangerous and/or not reasonably safe, and the Pinnacle Hip was in this defective condition at the time it left the hands of the Defendants. The Pinnacle Hip was expected to and did reach Ms. Burke and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

69. Ms. Burke was unaware of the significant hazards and defects in the Pinnacle Hip. The Pinnacle Hip was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. During the period that Ms. Burke used the Pinnacle Hip, it was being utilized in a manner that was intended by Defendants. At the time Ms. Burke had the Pinnacle Hip implanted it was represented to be safe and free from latent defects.

70. Defendants are strictly liable to Ms. Burke for designing, manufacturing, and placing into the stream of commerce the Pinnacle Hip, which was unreasonably dangerous for its reasonably foreseeable uses because of its design defects.

71. Defendants knew or should have known of the danger associated with the use of the Pinnacle Hip, as well as the defective nature of the Pinnacle Hip, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the Pinnacle Hip so as to maximize sales and profits at the expense of public health and safety, in conscious disregard of the foreseeable harm caused by the Pinnacle Hip.

72. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiffs in an amount to be determined at trial.

COUNT III
(Breach of Express Warranty)

73. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

74. Defendants advertised, labeled, marketed and promoted its product, the Pinnacle Hip, representing the quality to health care professionals, the FDA, Ms. Burke, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Pinnacle Hip would conform to the representations. More specifically, Defendants represented that the Pinnacle Hip was safe and effective for use by individuals such as Ms. Burke or that it was safe and effective to treat Ms. Burke's condition.

75. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

76. The Pinnacle Hip did not conform to the representations made by Defendant in the at the Pinnacle Hip was not safe and effective, was not safe and effective for use by individuals such as Ms. Burke, and/or was not safe and effective to treat in individuals, such as Ms. Burke.

77. At all relevant times, Ms. Burke used the Pinnacle Hip for the purpose and in the manner intended by Defendants.

78. Ms. Burke and her physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

79. The breach of the warranty was a substantial factor in bringing about Ms. Burke's injuries.

80. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

COUNT IV
(Products Liability Act – Breach of Implied Warranty)

81. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

82. The Pinnacle Hip was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Pinnacle Hip minimally safe for its intended purpose.

83. At all relevant times, Ms. Burke used the Pinnacle Hip for the purpose and in the manner intended by Defendants.

84. Ms. Burke and her physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

85. Defendants' breach of the implied warranty was a substantial factor in bringing about Ms. Burke's injuries.

86. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

DEMAND FOR JURY TRIAL

87. Plaintiff hereby demands a trial by jury as to all issues so triable.

WHEREFORE, Plaintiff demands judgment for the following:

1. Past and future medical and incidental expenses;

2. Past and future loss of earnings and/or earning capacity;

3. Past and future general damages;

4. Prejudgment and post judgment interest;

5. Disbursements and expenses of this action, including reasonable counsel fees and other appropriate relief; and

6. Such other and further relief as the court may deem just and proper.

Dated: April 29, 2015

MARTIN & JONES, PLLC

/s/ H. Forest Horne

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